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09/880,258	06/13/2001	Jane Sheetz	13977 (IND-039)	5090

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EXAMINER

LUONG, SHIAN TINH NHAN

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 01/05/2005

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,258

Applicant(s)

SHEETZ ET AL.

Examiner

Shian T. Luong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,12,14-19,21-27,30 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,12,14-19,21-27,30 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 16.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Allowable Subject Matter

1. Prosecution on the merits of this application is reopened for all the previous allowed claims as a result of the IDS submitted on 6/18/04. The claims are considered unpatentable for the reasons indicated below:

Claim Rejections - 35 USC § 112

2. Claims 1-8,12,14-19,21-27,30,32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 5, the claim requires the outer packaging tray not to be specific and yet it depends from claim 4 which requires the specific packaging tray to retain the particular surgical structure. The claims appear to be in contradiction with one another. In claim 15, the term "a flange" has been defined in claim 1 and the term "the upper perimeter" lacks proper antecedent basis. With regard to claims 1,17 and 23, the carrier and its bottom surface is not generally flat due to the various shaped relief areas and retainers. In claim 21, applicant should clarify whether the snap-fit recesses are the same as the parallel recess. Appropriate correction is required.

Claim Rejections - 35 USC § 103

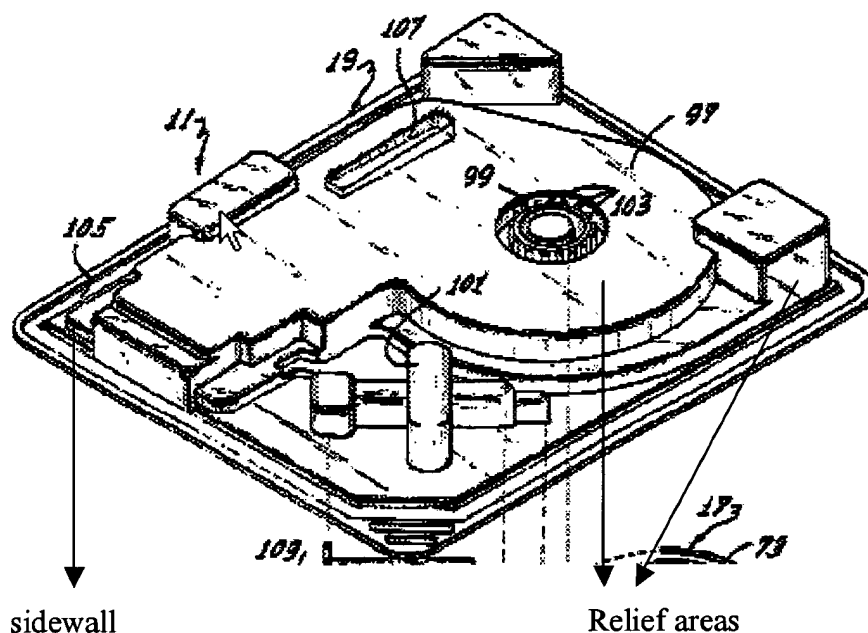
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2,4,5,12,18,19,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bickelhaupt et al. (US 4,713,059).

With respect to claim 1, a packaging arrangement comprising an outer packaging tray 19 and a carrier 13 which is inserted into the outer packaging tray for shipment or storage, and including a plurality of retainers 65 defining a series of parallel recesses. Each of the retainers holding a respective one of the coil loops in the recess defined by the retainer. The carrier provides increased ease of handling of the medical instrument by engaging the instrument at a series of separate locations along the length of the instrument. A selected length of the instrument can be removed from the carrier while remaining coils remain secured to the carrier. The outer packaging tray comprises a rectangular tray which is formed by plastic (column 2, line 55). The tray has a bottom surface, sidewalls, and a flange 105 at a top of and extending around the side walls. The bottom surface is generally flat with shaped relief areas (97 and the square and triangular portion adjacent thereto) defining one or more depressions to receive the carrier. The outer packaging tray is sealed with a top closure 21. Although the tray is not thermoformed, it would have been obvious to use any of a variety of methods to form the package including thermoforming. It is well settled that the patentability of a product ordinarily can not depend on its method of being made. See In re Thorpe.

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With respect to claim 2, the carrier defines connector end/treatment end retainers 63,45 for retaining a connector end and a treatment end of the instrument.

With respect to claims 4 and 5, the carrier is generic to a plurality of specific carrier and yet designed and contoured specific to a particular surgical device. For example, the surgical instrument can store an instrument with two probes and yet can also store an instrument with one probe. In addition, applicant has not claimed the combination of the instrument with the packaging arrangement and hence the package is capable of holding a specific or a variety of instruments.

With respect to claim 12, a first recess of the element 63 defines a tip receiver/protector, and a second recess of the element 45 defines a connector handle receiver/protector.

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With respect to claims 18-19, it would have been obvious to make the carrier out of any of a variety of shapes and sizes such as I shape or Y shape since a change in aesthetic (ornamental) design generally will not support patentability. In re Seid, 73 USPQ 431.

With respect to claim 21, a packaging arrangement comprising an outer packaging tray 19 and a carrier 13 which is inserted into the outer packaging tray for shipment or storage, and including a plurality of retainers 65 defining a series of parallel recesses. Each of the retainers holding a respective one of the coil loops in the recess defined by the retainer. The carrier provides increased ease of handling of the medical instrument by engaging the instrument at a series of separate locations along the length of the instrument. A selected length of the instrument can be removed from the carrier while remaining coils remain secured to the carrier. An end of the instrument seated in a top portion of the carrier in a recess formed by element 45 to match the profile of the end portion. Two opposed posts have a negative profile to match the end portion to retain the barrel in place. The recesses formed by element 65 retain the coils and one recess 63 has a larger size to retain the end of the instrument.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bickelhaupt et al. in view of Cerwin et al. (US 5,833,055). It is not clear whether the package of Bickelhaupt et al. as shown in Figure 1 is sterilizable. However, Cerwin et al teaches a sterilizable cover 128 made out of foil for a medical package. It would appear that the foil utilize in Bickelhaupt et al. would be able to function in the same manner for sterilization purpose since it is for storage of sterile instruments.

6. Claims 6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bickelhaupt et al. in view of Bierman (US 5,354,282). Although Bickelhaupt does not show an attachment

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means to attach the carrier to a surface, Bierman shows, as an example, a carrier with adhesive bottom side 18 to attach the carrier to a desired location. The adhesive is initially secured to a backing prior to usage. It would have been obvious in view of Bierman to provide adhesive on the bottom portion of the carrier to attach the carrier to a support to prevent unnecessary movement.

7. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bickelhaupt et al. in view of Official Notice. Although Bickelhaupt does not show a spring clip, it is conventionally known to use a spring clip to attach a receptacle to a surface. It would have been obvious to provide the spring clip on the carrier to attach the carrier to a support surface.

8. Claims 23-24,26,27,30,34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Admitted Prior Art in view of Bickelhaupt. Admitted Prior Art on pages 1-2 teaches that a fiberoptic cable is generally packaged and shipped as a coil. Admitted Prior Art does not disclose a plurality of parallel retainers defining a plurality of recesses. Bickelhaupt et al. teaches a packaging arrangement comprising an outer packaging tray 19 and a carrier 13 which is inserted into the outer packaging tray for shipment or storage, and including a plurality of retainers 65 defining a series of parallel recesses. Each of the retainers holding a respective one of the coil loops in the recess defined by the retainer. The carrier provides increased ease of handling of the medical instrument by engaging the instrument at a series of separate locations along the length of the instrument. A selected length of the instrument can be removed from the carrier while remaining coils remain secured to the carrier. The outer packaging tray comprises a rectangular tray which is formed by plastic (column 2, line 55). The tray has a bottom surface, sidewalls, and a flange 105 at a top of and extending around the side walls. The bottom surface

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is generally flat with shaped relief areas (97 and the square and triangular portion adjacent thereto) defining one or more depressions to receive the carrier. The retainers secure the article until it is removed by the user. It would have been obvious to provide retainers on the carrier of the Admitted Prior Art to secure the article in an organized manner prior to dispensing.

With respect to claims 24 and 30, it would have been obvious to secure the connector end of the fiberoptic cable to the carrier with a connector end retainer 45 on the carrier, and securing a treatment end of the fiberoptic cable to the carrier with the treatment end retainer 63 on the carrier. One of ordinary skill in the art would insert the coils of the fiberoptic cables and the connector end/treatment end in similar manner as shown by Bickelhaupt et al.

With respect to claim 26, the carrier is generic to a plurality of specific carrier and yet designed and contoured specific to a particular surgical device. For example, the surgical instrument can store an instrument with two probes and yet can also store an instrument with one probe. In addition, applicant has not claimed the combination of the instrument with the packaging arrangement and hence the package is capable of holding a specific or a variety of instruments.

With respect to claim 27, it would have been obvious to secure the fiberoptic coil to the carrier with a plurality of individual coil loop retainers 65 which are molded in the carrier (column 2, line 55), each of which retains and secures a single coil loop of the fiberoptic coil, which allows each individual coil loop to be individually released from the carrier. One of ordinary skill in the art would insert the coils of the fiberoptic cables and the connector end/treatment end in similar manner as shown by Bickelhaupt et al.

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With respect to claim 34, the method step of Bickelhaupt et al. includes sealing the cover 21 to the housing flange 19.

9. Claims 23-24,26,27,30,34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bickelhaupt in view of Admitted Prior Art. Bickelhaupt et al. teaches a packaging arrangement comprising an outer packaging tray 19 and a carrier 13 which is inserted into the outer packaging tray for shipment or storage, and including a plurality of retainers 65 defining a series of parallel recesses. Each of the retainers holding a respective one of the coil loops in the recess defined by the retainer. The carrier provides increased ease of handling of the medical instrument by engaging the instrument at a series of separate locations along the length of the instrument. A selected length of the instrument can be removed from the carrier while remaining coils remain secured to the carrier. The outer packaging tray comprises a rectangular tray which is formed by plastic (column 2, line 55). The tray has a bottom surface, sidewalls, and a flange 105 at a top of and extending around the side walls. The bottom surface is generally flat with shaped relief areas (97 and the square and triangular portion adjacent thereto) defining one or more depressions to receive the carrier. The retainers secure the article until it is removed by the user. Although Bickelhaupt et al. does not disclose the fiberoptic coil, Admitted Prior Art on pages 1-2 teaches that a fiberoptic cable is generally packaged and shipped as a coil. It would have been obvious to store the fiberoptic coil on the carrier of the Bickelhaupt et al. to secure the article in an organized manner prior to dispensing.

With respect to claims 24 and 30, it would have been obvious to secure the connector end of the fiberoptic cable to the carrier with a connector end retainer 45 on the carrier, and securing a treatment end of the fiberoptic cable to the carrier with the treatment end retainer 63 on the

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carrier. One of ordinary skill in the art would insert the coils of the fiberoptic cables and the connector end/treatment end in similar manner as shown by Bickelhaupt et al.

With respect to claim 26, the carrier is generic to a plurality of specific carrier and yet designed and contoured specific to a particular surgical device. For example, the surgical instrument can store an instrument with two probes and yet can also store an instrument with one probe. In addition, applicant has not claimed the combination of the instrument with the packaging arrangement and hence the package is capable of holding a specific or a variety of instruments.

With respect to claim 27, it would have been obvious to secure the fiberoptic coil to the carrier with a plurality of individual coil loop retainers 65 which are molded in the carrier (column 2, line 55), each of which retains and secures a single coil loop of the fiberoptic coil, which allows each individual coil loop to be individually released from the carrier. One of ordinary skill in the art would insert the coils of the fiberoptic cables and the connector end/treatment end in similar manner as shown by Bickelhaupt et al.

With respect to claim 34, the method step of Bickelhaupt et al. includes sealing the cover 21 to the housing flange 19.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bickelhaupt et al. in view of Kirk Banerian (WO 99/67156). Bickelhaupt et al. does not disclose three offsets in the recess as recited in claim 22. However, Banerian teaches a container for storing guide wire or other flexible, elongated medical device between uses during medical procedures. The container has a base 112 with a plurality of clips 134 configured so that guide wire 126 can be placed into and retained within openings 136. The wire is retained in a coiled position so that the

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wire does not contact itself. Each clip 134 has three openings or recesses. Therefore, it would have been obvious in view of Banerian to provide additional recesses with additional openings to allow securement or longer coils of the fiberoptic cable.

11. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references applied above with respect to claim 23, further in view of Cerwin et al. (US 5,833,055). It is not clear whether the package of Admitted Prior Art or Bickelhaupt et al. as shown in Figure 1 is sterilizable. However, Cerwin et al teaches a sterilizable cover 128 made out of foil for a medical package. It would have been obvious to provide a material that function in the same manner for sterilization purpose since it is for storage of sterile instruments.

Allowable Subject Matter

12. Claims 14-17,32-33 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

13. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel and not to the examiners. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information without contacting the examiners, M.P.E.P. 203.08. The **Group clerical receptionist number is (703) 308-1148.**


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If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers should be directed to Donna Monroe at (703) 308-2209.

For applicant's convenience, the official FAX number is (703) 872-9306. This practice may be used for filing papers not requiring a fee. It may also be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify Examiner Luong of Art Unit 3728 at the top of your cover sheet of any correspondence submitted.

Inquiries concerning the merits of the examination should be directed to Shian Luong whose telephone number is (571) 272-4557. The examiner can normally be reached on M-H from 7:00am to 4:00pm EST.

STL
December 21, 2004


Primary Examiner
Shian Luong
Art Unit 3728